IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, AND CENTER FOR NEUROLOGIC STUDY,	:	
Plaintiffs,	:	
v.	:	
ACTAVIS SOUTH ATLANTIC LLC, ACTAVIS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., IMPAX LABORATORIES, INC., WOCKHARDT, LTD., WOCKHARDT USA, LLC, WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND WATSON PHARMA, INC.,	:	C.A. No. 11-704-LPS (CONSOLIDATED)
Defendants.	:	

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MEMORANDUM OPINION

December 3, 2012
Wilmington, Delaware.

STARK, U.S. District Judge:

Avanir Pharmaceuticals, Inc., Avanir Holding Company, and Center for Neurologic Study (collectively, "Avanir" or "Plaintiffs") filed this patent infringement action against Actavis South Atlantic LLC, Actavis, Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Impax Laboratories, Inc., Wockhardt, Ltd.,Wockhardt USA, LLC, Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (collectively, "Defendants") on August 10, 2011.[1] (D.I. 1)

Pending before the Court is the issue of claim construction of various disputed terms found in U.S. Patent Nos. RE38,115 (the "'115 patent") and 7,659,282 (the "'282 patent"). The '115 patent relates to formulations containing dextromethorphan and quinidine, the active ingredients of Avanir's Nuedexta® product. The '282 patent relates to the use of dextromethorphan and quinidine for the treatment of a neurological disorder.

The parties completed briefing on claim construction on September 14, 2012. (D.I. 116, 118, 138, 139) The Court held a *Markman* hearing on October 5, 2012. *See Markman* Hr'g Tr., October 5, 2012 (D.I. 168) (hereinafter "Tr.").

LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312

[1]Civil Action No. 11-704 against defendants Actavis South Atlantic LLC and Actavis, Inc.; Civil Action No. 11-705 against defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.; Civil Action No. 11-757 against defendant Impax Laboratories, Inc.; and Civil Action No. 11-758 against defendants Wockhardt, Ltd. and Wockhardt USA, LLC were consolidated on September 26, 2011. Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. were added on July 11, 2012. (D.I. 21; D.I. 103)

(Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-

15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

A court also may rely on "extrinsic evidence," which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and

learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

CONSTRUCTION OF DISPUTED TERMS

I. The '115 Patent

Claim 18 of the '115 patent, with the disputed terms highlighted, is as follows:

> ***A unit dosage formulation for treatment of chronic or intractable pain***, comprising: (a) dextromethorphan or a pharmaceutically acceptable salt thereof, and, (b) ***a debrisoquin hydroxylase inhibitor***, in ***a combined form that is designed for oral ingestion by humans, wherein the dextromethorphan or salt thereof and the debrisoquin hydroxylase inhibitor are present at a combined dosage which renders the dextromethorphan therapeutically effective in substantially reducing chronic or intractable pain, without causing unacceptable side effects.***

A. "A unit dosage formulation for treatment of chronic or intractable pain"

Plaintiffs' Proposed Construction: The preamble is not a claim limitation; needs no construction.

Defendants' Proposed Construction: "A unit dosage formulation intended to treat chronic or intractable pain"

Court's Construction: The preamble is not a claim limitation; needs no construction.

The parties disagree on whether this disputed term, the preamble of claim 18, is a limitation of the claim. The Court is persuaded by Plaintiffs' argument that the preamble is not a limitation and, therefore, does not require construction.

"No litmus test defines when a preamble limits claim scope." *Catalina Mktg. Int'l v. Coolsavings.com*, 289 F.3d 801, 808 (Fed. Cir. 2002). Nonetheless, *Catalina* established several factors for courts to consider in determining the effect of a preamble. For example, "a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state the purpose or intended use for the invention." *Id.* (internal quotation marks omitted). Plaintiffs assert, and the Court agrees, that the body of claim 18

provides a structurally complete formulation of the invention. The deletion of the preamble would not change the claimed invention.

Other of the *Catalina* guideposts are also not satisfied. The preamble does not recite an essential structure, is not essential to understanding the claim body, and is not necessary to give meaning to the claim. *See Catalina*, 289 F.3d 801 at 808. Nor have Defendants provided evidence of "clear reliance on the preamble during prosecution to distinguish the claimed invention from prior art . . . ." *Id.*

A preamble may also be a claim limitation when it adds, limits, or otherwise further defines the subject matter of the invention. *See Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995). Here, again, as the deletion of the preamble has no effect on the scope of the claim, it is not limiting.

B. "A debrisoquin hydroxylase inhibitor"

Plaintiffs' Proposed Construction: "A cytochrome P-450 2D6 inhibitor, excluding cimetidine"

Defendants' Proposed Construction: "A compound capable of inhibiting the oxidation of dextromethorphan by the liver enzyme debrisoquin hydroxylase"

Court's Construction: "A compound capable of inhibiting the oxidation of dextromethorphan by the liver enzyme debrisoquin hydroxylase, excluding cimetidine"

The parties raise two disputes: "(1) whether the specification's lexicography controls; and (2) whether cimetidine should be included as a debrisoquin hydroxylase inhibitor ('DHI')." (D.I. 138 at 10)[2]

[2]Plaintiffs suggest that only the second of these is really an issue, contending that the parties' constructions are "substantially similar" so the only dispute is whether cimetidine is excluded. (D.I. 139 at 14)

On the first issue, the Court agrees with Defendants that the specification's lexicography controls. The '115 specification states that the "particular enzyme primarily responsible for DM [dextromethorphan] oxidation is debrisoquin hydroxylase" and then lists several of its synonyms. (*See* '115 patent col. 3 ll. 51-55) The "Definitions" section of the specification defines "oxidative inhibitors" as referring to "inhibitors capable of inhibiting the oxidation of DM by the liver enzyme debrisoquin hydroxylase." (*See id.* at col. 2 ll. 22-25) Defendants' construction properly tracks this comprehensive definition as stated in the specification and the Court adopts it.

On the second issue, the Court agrees with Plaintiffs that the prosecution history supports excluding cimetidine. In an office action, the PTO rejected the patentees' claims pursuant to 35 U.S.C. § 102 based on a prior art patent disclosing dextromethorphan in combination with cimetidine. (D.I. 110 Ex. C at AVAN-0002144-45) In response, the patentees stated that "all references to cimetidine as a debrisoquin hydroxylase inhibitor have been deleted." (*Id.* at AVAN-0002145) Thereafter, all references to cimetidine were removed from the original claim language. (Tr. at 101-02) The Court is persuaded that the patentees made a "clear and unmistakable disclaimer" of cimetidine. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003).

C. "A combined dosage which renders the dextromethorphan therapeutically effective in substantially reducing chronic or intractable pain without causing unacceptable side effects"

Plaintiffs' Proposed Construction: This is not a single claim term and is not amenable to construction; instead, it should be construed by reference to the individual claim term contained therein:

(1) "a combined dosage;"

(2) "which renders;"

(3) "the dextromethorphan;"

(4) "therapeutically effective,"

(5) "in,"

(6) "substantially reducing,"

(7) "chronic pain,"

(8) "intractable pain," and

(9) "without causing unacceptable side effects."

Avanir asserts that except for "chronic pain" and "intractable pain" (as separately defined) each of these terms needs no construction and has its ordinary meaning.

Defendants' Proposed Constructions: "About 20 mg/day to about 200 mg/day of dextromethorphan or salt thereof and 50 mg/day to 300 mg/day of the debrisoquin hydroxylase inhibitor (DHI) quinidine for treatment of chronic or intractable pain. Dosages of other DHIs will vary with the DHI, and should be determined on an individual basis using the protocol described in Example 4."

To the extent Defendants' construction is not adopted and "substantially reducing chronic or intractable pain" needs further construction, it is indefinite and/or does not otherwise satisfy the requirements of 35 U.S.C. § 112.

To the extent Defendants' construction is not adopted and "without causing unacceptable side effects" needs further construction, it is indefinite and/or does not otherwise satisfy the requirements of 35 U.S.C. § 112.

Court's Construction: No construction necessary. Plain and ordinary meaning.

"[W]hen a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006). Here, adopting Defendants' proposed dosage of quinidine of between 50 mg/day to 300 mg/day would lead to the improper result of independent claim 18 having narrower claim scope than dependent claim 21, which depends from claim 18. Dependent claim 21 claims a dosage of quinidine of 300 mg/day or less, a range that would include 0 to 49 mg/day. Defendants' construction, however, would mean that claim 18 is limited to dosages of quinidine no lower than 50 mg/day – that is, narrower claim scope than claim 21.

The Court is also unpersuaded by Defendants' contention that language such as "this invention" or "the present invention" in the patent's specification limits the claims to the precise scope proposed by Defendants. The terms "this invention" or "the present invention" are used in the patent more than ten times, yet Defendants find the terms to be limiting of claim scope only twice. In those two instances – "[t]his invention ***anticipates***" and "[t]he present invention ***contemplates***" certain dosages ('115 patent col. 4 ll. 9-11, 26-29) (emphasis added) – the terms are not used in a manner suggestive of comprehensive descriptions of the scope of the invention as a whole. *See Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007).

Defendants alternatively propose that two terms within the larger term require construction: "substantially reducing chronic or intractable pain" and "without causing

unacceptable side effects."[3] Defendants further contend that these two terms are invalid due to indefiniteness. The Court is not persuaded. *See generally Personalized User Model LLP v. Google, Inc.*, 2012 WL 295048, at *22 (D. Del. Jan. 25, 2012) (stating Court "does not permit summary judgment arguments, including indefiniteness arguments, during the claim construction phase of the litigation"). A claim is "sufficiently definite to survive claim construction" unless the term is "insolubly ambiguous." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008); *see also Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 2003 WL 124149, at *1 n.1 (D. Del. Jan. 13, 2003). Defendants have failed to establish "by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton*, 514 F.3d at 1249. To the contrary, the Court construes these terms by adopting their plain and ordinary meaning, which is appropriate here as there is no basis in the claims, specification, or prosecution history to depart from the plain and ordinary meaning of these terms. *See Thorner v. Sony Computer Entertainment Am. LLC*, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012).

The parties previously disputed the terms "chronic pain" and "intractable pain." After the hearing, the parties agreed to the meaning of these terms. (D.I. 165) "Chronic pain" will be construed to mean "long-term pain resulting from conditions such as stroke, cancer and trauma,

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[3]Defendants' suggestion that this Court's decision in construing an entirely unrelated patent, in response to arguments made by parties with no connection to the instant dispute, should lead the Court to a similar conclusion here is unavailing. (*See* D.I. 138 at 6-7) (citing *Cadence Pharm., Inc. v. Paddock Labs Inc.*, 2012 WL 3609687, at *5 (D. Del. Aug. 22, 2012)) (construing entire phrase, rather than terms within it, to better preserve coherence of patent and reduce risk of inconsistencies)

as well as neuropathic pain due to deterioration of nerve tissue such as postherpetic neuralgia (PHN) resulting from herpes zoster infection, and diabetic neuropathy resulting from long-time diabetes. The conditions are not an exclusive list." "Intractable pain" will be construed to mean "pain which failed to respond adequately to conventional treatments."

II. The '282 Patent

Claim 1 of the '282 patent, highlighted to show the terms in dispute, is as follows:

> ***A method for treating pseudobulbar affect or emotional lability***, the method comprising administering to a patient in need thereof ***dextromethorphan in combination with quinidine***, wherein the amount of dextromethorphan administered comprises from about 20 mg/day to about 80 mg/day and wherein the amount of quinidine administered comprises from about 10 mg/day to less than about 30 mg/day with the proviso that the weight to weight ratio of dextromethorphan to quinidine is 1:0.5 or less.

A. "A method for treating pseudobulbar affect or emotional lability"

Plaintiffs' Proposed Construction: "A method for treating a neurological disorder characterized by intermittent spasmodic outbursts of emotion at inappropriate times or in the absence of any particular provocation"

Defendants' Proposed Construction: "A method for treating the condition known as pseudobulbar affect or emotional lability (also referred to by the terms emotionalism, emotional incontinence, emotional discontrol, excessive emotionalism, and pathological laughing and crying), which is characterized by intermittent spasmodic emotional outbursts at inappropriate times or in the absence of any particular provocation"

Court's Construction: "A method for treating a neurological disorder characterized by intermittent spasmodic outbursts of emotion at inappropriate times or in the absence of any particular provocation"

The parties have two disputes: (1) whether the construction should include neurological disorders characterized by specific symptoms, and (2) whether the construction should include

synonyms of the condition.[4] The Court agrees with Plaintiffs on both issues.

The term "neurological disorders" is found in the specification. The Field of Invention states that "compositions and methods for treating neurological disorders are provided." ('282 patent col. 1 ll. 18-19) Likewise, the patent is entitled, "Pharmaceutical Compositions . . . for the Treatment of Neurological Disorders." The parties agree that pseudobulbar affect or emotional lability is a neurological disorder characterized in the patent as "intermittent spasmodic outbursts of emotion at inappropriate times or in the absence of any particular provocation." (*See id.* at col. 1 ll. 18-19; Tr. at 136, 139) The Court's construction properly identifies pseudobulbar affect and emotional lability as neurological disorders characterized by the agreed upon symptoms, thus "stay[ing] true to the claim language and most naturally align[ing] with the patent's description of the invention." *Phillips*, 415 F.3d at 1315.

In the context of this patent claim term, including a list of synonyms is not helpful. Defendants' contention that failing to list the synonyms truncates the specification's definition is unconvincing. The specification defines emotional lability as "characterized by intermittent spasmodic outbursts of emotion . . . at inappropriate times or in the absence of any particular provocation." ('282 patent col. 1 ll. 39-40) The specification then goes on to list synonyms of the condition, but the synonyms are not part of the definition. (*See id.* at col. 1 ll. 44-47)

[4]The parties agree that this preamble is limiting, although they do not agree on the reason why it is limiting. (D.I. 116 at 17; D.I. 138 at 15-17; Tr. at 138)

B. "Dextromethorphan in combination with quinidine"

Plaintiffs' Proposed Construction: "Dextromethorphan and quinidine given in a combined dose, or in separate doses administered substantially simultaneously"

Defendants' Proposed Construction: "Dextromethorphan and quinidine co-administered in combined or separated doses"

Court's Construction: "Dextromethorphan and quinidine given in a combined dose, or in separate doses administered substantially simultaneously"

The parties agree that dextromethorphan and quinidine can be administered together or separately, but disagree on how the separate doses may be administered. The Court agrees with Plaintiffs that separate doses may be administered substantially simultaneously.

The Court's construction is supported by the specification and evidence cited in the patent. The specification states that separate doses are "administered substantially simultaneously" or "simultaneously." ('282 patent col. 15 ll. 20-22, 40-41) While the specification also uses the term "co-administration," this term is not contained in the claims, and the Court sees no reason to narrow the claims to require co-administration.

IV. CONCLUSION

For the foregoing reasons, the Court will construe the claim terms in the '115 and '282 patents consistent with this Memorandum Opinion. An appropriate Order follows.